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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,311	06/22/2001	Jeffry G. Weers	0103.00	9537

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INHALE THERAPEUTIC SYSTEMS, INC  
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EXAMINER

WEBMAN, EDWARD J

ART UNIT PAPER NUMBER

1617

DATE MAILED: 01/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/888311

Applicant(s)

W66RS

Examiner

W66MM

Group Art Unit

1617

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 9/30/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 4-12, 15-29 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 4-12, 15-29 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 6, 7, 9
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-29 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/16419 (WO '419)

WO '419 teaches delivery of particles in a DPI (abstract). A bulk density less than  $0.5\text{g/cm}^3$  is disclosed (page 9 line 25). Perforations are disclosed (page 3 lines 25-26). Any active is specified (page 13 lines 21-24). Antibiotics (page 14 line 15) and Budesonide (page 14 line 25) are disclosed. DPSC is specified (page 11 line 6). A geometric size of 1-5 microns is disclosed (page 24 lines 18-20). Hollow particles are specified (page 54 line 24). A 99.8% particle size of 2.2 microns with a DPI is disclosed (Table VI page 62). Upon a single actuation (page 62 line 13). A fine particle fraction of 87% is specified (page 62 line 28).

As to the claimed Tmax, such a property is inherent in the method given that the prior art device and particles are the same as those claimed.

Claims 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al (WO 98/31346).

Edwards et al. (WO 98/31346) discloses delivery of phospholipid matrix containing particles with a mass mean diameter between 5 and 30 microns and a tap (bulk) density of  $0.4\text{g/cm}^3$  which together yield an aerodynamic diameter of the particles of between 1 and 5 microns for use in a method of administration employing a passive

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dry powder inhaler (see abstract, lines 3-9, p. 6, lines 2-13, p. 8, lines 11-21, p.9, lines 12-13, p. 11, lines 23-27, p.33, lines 23-29). Any agent can be incorporated (page 20 line 1-page 21 line 14). Over 35% of particles are considered respirable (page 34 lines 12-14). As to applicants' claimed properties, the disclosed inhaler of commerce in combination with the disclosed particles, inherently provides the same delivery characteristics as claimed with like commercially available devices disclosed by applicants.

Applicants argue that Edwards et al teach delayed release whereas applicants claim a Tmax less than 15 minutes. However, a applicants do not disclose a Tmax of 14 minutes is a delayed release as compared to an immediate release.

The disclosure is objected to because of the following informalities: Nowhere in the specification is Tmax defined.

Appropriate correction is required.

Claims 4-12, 21-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"substantially" is vague; what percent?

No claims allowed.

Items FW-FY on page 9 PTO form 1449, filed 6/3/02 were lined through because publication dates were not provided.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward Webman whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday to Friday 9 Am 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, S. Padmanabhan can be reached on (703) 308-0570. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3592 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Webman/LR  
December 17, 2002

  
EDWARD WEBMAN  
PATENT EXAMINER  
GROUP 1500